

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucose 5 g/100 ml B. Braun Vet Care solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats

GlucosaVet 5g/100 ml solución para perfusión para bovino, caballos, ovino, caprino, porcino, perros y gatos (Spain)

Glucose B. Braun Vet Care 5 g/100 ml Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Schweine, Hunde und Katzen (Austria, Germany)

Glucose 5 g/100 ml B. Braun Vet Care solution pour perfusion pour bovins, chevaux, ovins, caprins, porcins, chiens et chats (Belgium)

Glucose 5 g/100 ml B. Braun Vet Care solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats (United Kingdom/Ireland)

Glucosio 5 g/100 ml B. Braun Vet Care soluzione per infusione per bovini, cavalli, pecore, capre, suini, cani e gatti (Italy)

Glucose 5 g/100 ml B. Braun Vet Care oplossing voor infusievoor runderen, paarden, schapen, geiten, varkens, honden en katten (Netherlands)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contains:

Active substance:

Glucose monohydrate 5.5 g
(equivalent to anhydrous glucose 5.0 g)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

Clear, colourless or almost colourless aqueous solution, free from visible particles

Caloric value	837 kJ/l = 200 kcal/l
Theoretical osmolarity	278 mOsm/l
pH value	3.5 - 5.5

4. CLINICAL PARTICULARS

4.1 Targets species

Cattle, horses, sheep, goats, pigs, dogs and cats

4.2 Indications for use, specifying the targets species

Cattle, horses, sheep, goats, pigs, dogs and cats:

- Treatment of dehydration (in the absence of shock)
- Parenteral rehydration
- Correction of hypernatremia
- Correction of hyperkalaemia
- Transient supportive treatment of hypoglycaemia

4.3 Contraindications

Do not administer to hyperglycaemic animals.

This product is unsuitable for the correction of hypotonic dehydration. Do not use in animals with pre-existing peripheral oedema caused by a reduction in intravascular oncotic pressure. This product is not suitable as a sole source of calorie requirements or as a substitute for oral or parenteral nutrition.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animal

This product does not contain electrolytes. Care should be taken to closely monitor electrolyte and phosphate balance in patients undergoing infusion of this product, and to adjust treatment accordingly.

This product should be used with particular caution in patients with the following conditions:

Diabetes mellitus

Intracranial or intraspinal bleeding

Anuria

Addison's disease

Severe or long standing hypernatraemia should be corrected gradually.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None

4.6 Adverse reactions (frequency and seriousness)

In very rare cases administration of products by intravenous infusion may increase the risk of thrombosis.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s)).
- Common (more than 1 but less than 10 animals in 100 animals treated).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated).
- Rare (more than 1 but less than 10 animals in 10,000 animals treated).
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy or lactation

Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Incompatibilities with certain antibiotics (e.g. beta-lactam antibiotics, tetracyclines, sulfadiazine sodium) and heparin are recognised.

4.9 Amounts to be administered and administration route

Intravenous use. Administer slowly via intravenous infusion.

This product should not be administered at a rate in excess of 10 ml/kg bodyweight/hour, otherwise glycosuria and osmotic diuresis may result.

Infusion rates should be calculated according to the presenting condition, bodyweight and degree of dehydration of the animal being treated.

The total fluid volume to be administered should consider existing deficits, maintenance requirements and ongoing losses.

IV fluids should be warmed up to body temperature prior to administration.

Maintain aseptic precautions throughout administration.

For single use only.

Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overperfusion can lead to overhydration, hypertension and extravascular fluid accumulation. Symptoms may include respiratory distress. In the case of overperfusion, reduce or cease fluid infusion and administer oxygen, diuretics and adjunctive treatment as necessary. Monitor respiration and heart rate, fluid output, electrolyte balance and blood glucose during administration.

The administration of excess glucose can lead to hyperglycaemia, glycosuria and polyuria.

4.11 Withdrawal period(s)

Meat and offal: Zero days

Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: blood substitutes and perfusion solutions - solutions for parenteral nutrition

ATCvet code: QB05BA03

5.1 Pharmacodynamic properties

Glucose 5 g/100 ml infusion is used as a replacement source of water and glucose for animals that cannot be given rehydration fluids orally. It is isotonic on initial administration, (thereby avoiding causing osmotic shock to red blood cells), and the glucose is then metabolised to water, resulting in a net effect of administration of a hypotonic solution. The glucose can provide a transient source of nutrient and will aid in correction of hyperkalaemia. The calorie content is 17 kJ/g or 4 kcal/g of glucose.

5.2 Pharmacokinetic particulars

Intravenous infusion ensures rapid distribution. The constituents of the infusion solution are metabolised and excreted through the same pathways as water and glucose derived from normal dietary sources.

6. PHARMACEUTICALS PARTICULARS

6.1 List of excipients

Water for injections

6.2 Major incompatibilities

The medicinal product is incompatible with calcium-disodium edetate, histamine diphosphate, sodium warfarin and sodium thiopental.

The mixture with other medicinal products may cause incompatibilities. Checking the compatibility of any mixture is the responsibility of the user.

Glucose solutions should not be administered through the same infusion equipment simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Use immediately after opening the bottle. Dispose of any unused product.

6.4 Special precautions for storage

Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene bottles of 100, 250, 500 and 1000 ml of capacity.

The additional closure cap on top of the sealed polyethylene container is made from high density polyethylene. Between the container and the closure cap an elastomeric latex free disk is placed.

Pack sizes:

Bottle of 100 ml

Bottle of 250 ml

Bottle of 500 ml

Bottle of 1000 ml

1 cardboard box containing 20 bottles of 100 ml

1 cardboard box containing 20 bottles of 250 ml

1 cardboard box containing 10 bottles of 500 ml

1 cardboard box containing 10 bottles of 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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08191 Rubí. (Barcelona), Spain

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Germany

Postal address:

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8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Prescription conditions: **To be supplied only on veterinary prescription.**

Administration conditions: **To be administered only by a veterinary surgeon.**